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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,256	09/13/2005	Angus Moodycliffe	115808-524	3290
29157 7590 05/01/2008 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER SHIN, DANA H	
			ART UNIT 1635	PAPER NUMBER
			NOTIFICATION DATE 05/01/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,256	<b>Applicant(s)</b> MOODYCLIFFE ET AL.	
	<b>Examiner</b> DANA SHIN	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

This Office action is in response to the communications filed on March 26, 2008.

Currently, claims 1-3 and 6-8 are under examination on the merits.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

#### ***Claim Rejections - 35 USC § 112***

Claims 1-3 and 6-8 remain rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement for the reasons of record as set forth in the Office action mailed on December 26, 2007 and for the reasons stated below.

Applicant's arguments filed on March 26, 2008 have been fully considered but they are not persuasive. Applicant argues that "it is well known and described in the specification that glucosylceramide synthase is associated with epithelial tissue damage, that the regulation of

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glucosylceramides in maintaining epithelial cell homeostasis is related to preventing/treating epithelial damage by silencing glucosylceramide synthase expression, and that reducing epithelial cell proliferation is related to preventing/treating epithelial damage”. Contrary to applicant's argument that the relationship between glucosylceramide synthase and epithelial cell damage is not only “well known” but also “well described”, the specification, as repeatedly pointed out in previous Office actions, mentions the claimed gene only once on page 10 throughout the entire disclosure of the specification. To reiterate, page 10, lines 15-19 describe that reducing glucosylceramide synthase mRNA by an antisense polynucleotide turns down the signal to epithelial cells to proliferate. Hence, reduced level of glucosylceramide synthase mRNA expression was described as being associated with reduced rate of epithelial cell proliferation. As such, it is questionable how applicant is able to assert that the reduction of glucosylceramide synthase mRNA expression will render prevention/treatment of “epithelial tissue damage” possible. Furthermore, applicant has not pointed out any particular teachings (specific page numbers) with regard to applicant's allegation that the specification provides an enabling disclosure for the claimed composition for treating/preventing epithelial tissue damage by a complementary RNA polynucleotide sequence to glucosylceramide synthase mRNA. The fact that the glucosylceramide synthase mRNA sequence was known in the art and that antisense technology was known in the art does not render the instantly claimed invention automatically enabled. See the detailed reasons on pages 4-6 of the Office action dated December 26, 2007 and pages 5-7 of the Office action dated July 26, 2007.

Applicant further asserts that reduction of glucosylceramide synthase mRNA that results in the reduced availability of glycosylceramides to CD<sub>1d</sub> binding blocks the function of CD<sub>1d</sub> to

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support the survival and propagation of damaged epidermal cells, thus preventing or treating epithelial tissue damage. Again, applicant's assertion is entirely based on applicant's own deductions and inferences and opinions, not on scientific facts. There is no teaching, let alone evidence, in the specification or in the prior art that reduction of glucosylceramide synthase mRNA expression results in treatment/prevention of epithelial tissue damage.

Since applicant has failed to demonstrate why the claimed invention is fully enabled at the time of the invention despite the insufficient knowledge pertaining to the claimed invention in the art, unpredictability of antisense/gene therapy art, and the complete lack of direction/working examples provided by the inventors, this rejection is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin  
Examiner  
Art Unit 1635

/J. E. Angell/  
Primary Examiner, Art Unit 1635